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The New Approach to the Elimination of Technical Barriers in the European Community

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I. INTRODUCTION

The intention of the European Community ("EC") to complete the internal market by December 31, 1992 includes a legislative program to abolish all technical barriers to the free movement of goods in the EC. Elimination of technical barriers is not a new goal for the EC. As early as 1969, the Council of Ministers of the European Communities ("Council of Ministers") adopted a General Program for the elimination of technical barriers,[1] but few results were actually achieved. In fact, the EC witnessed considerable growth in technical regulations and standards[2] which led to further fragmentation of the EC market. When the Commission of the European Communities ("Commission") published its White Paper *Completing the Internal Market*, it

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1. 12 J.O. COMM. EUR. (No. C 76) 1 (1969) ("Programme Général du 28 mai 1969 en vue de l'élimination des entraves techniques aux échanges résultant de disparités entre les dispositions législatives, réglementaires et administratives des Etats membres.").

2. A technical standard is a technical specification approved by a recognized standardizing body, with which compliance is not compulsory; a technical regulation is a technical specification, the observance of which is compulsory. *See Council Directive 83/189/EEC*, 26 O.J. EUR. COMM. (No. L 109) 8 (1983), at art. 1 (laying down a procedure for providing information in the field of technical standards and regulations) *as amended by* 29 O.J. EUR. COMM. (No. L 81) 75 (1988). *See also* GATT Agreement on Technical Barriers to Trade, GATT BISD, 26th Supp. 8 (1979).

had to recognize the failure of its previous harmonization policy.[3]

The profusion of different technical regulations and standards causes significant costs to companies, public authorities, consumers and taxpayers. For companies, these costs include duplication of the cost of research and development; loss of manufacturing efficiency as production runs have to be adapted to different needs; increased inventory and distribution costs; and competition weaknesses on world markets as a result of the small home market base. It was once estimated that there are over 100,000 different technical regulations and standards in the EC*.[4] The Cecchini Report demonstrates that companies consider these divergent technical regulations and standards as one of the most acute problems of European operations.[5] It has, for example, been estimated that no less than 300 million U.S. dollars is added to the product development costs of a passenger car because of divergent national specifications in Europe.[6]

For public authorities, the costs largely involve duplication of testing, certification and other enforcement costs. For the consumers and taxpayers the costs include direct costs, initially borne by producers and governments, that translate into high prices and taxes and indirect losses due to less competition and rationalization in production and marketing structures in Europe.[7]

This article deals with the abolition of technical barriers resulting from divergent national technical regulations and standards and divergent national testing and certification procedures with regard to industrial products.

Section II shows how the case law of the Court of Justice of the European Communities ("Court of Justice") regarding the free movement of goods has laid the foundations for a new approach to technical harmonization. This new approach was endorsed by the Council of Ministers in 1985 and has been made a center-piece strategy in achieving the purposes set forth in the 1985 White Paper.

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3. *Completing the Internal Market, White Paper from the Commission to the European Council* (Milan, June 28 & 29, 1985), COM (85) 310 final 18 (1985).

4. THE ECONOMICS OF 1992, European Economy No. 35, at 49 (1989). *See also* F. NICOLAS & J. REPUSSARD, COMMON STANDARDS FOR ENTERPRISES 26 (1988).

5. P. CECCHINI, THE EUROPEAN CHALLENGE, 1992: THE BENEFITS OF A SINGLE MARKET 24 (1988).

6. *Id.* at 27.

7. THE ECONOMICS OF 1992, *supra* note 4, at 49.

Section III explores the legal basis for harmonization. The EEC Treaty provisions which allow the EC institutions to harmonize national laws with a view to eliminating technical barriers to intra-EC trade in goods are described.

Section IV discusses the progress from the 1969 General Program to the 1985 approach of technical harmonization. Section V analyzes the essential structure of the new approach, and Section VI explains the role of the European standardization bodies. The EC's newly proposed approach to solving conformity assessment is reviewed in Section VII. Section VIII discusses the EC's mechanism for monitoring new national technical regulations and standards.

II. The Elimination of Technical Barriers in the EEC Treaty, as Applied by the Court of Justice

Article 8A of the EEC Treaty[8]* provides that "the Community shall adopt measures with the aim of progressively establishing an area without internal frontiers over a period expiring on 31 December 1992."[9]

The EEC Treaty distinguishes between the following internal trade barriers: customs duties and charges having equivalent effect (Article 9) and quantitative restrictions and measures having equivalent effect (Article 30). The EEC Treaty prohibits both kinds of trade barriers. While customs duties and charges are unconditionally prohibited, the prohibition of quantitative restrictions and measures having equivalent effect is subject to statutory and judge-made exceptions.

According to the Court of Justice, "measures having equivalent effect" is a catch-all category which covers any measure which is capable of hindering, directly or indirectly, actually or potentially, intra-EC trade.[10] For example, an administrative practice may constitute a measure having an equivalent effect.[11]

Technical barriers resulting from divergent national techni-

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8. Treaty Establishing the European Economic Community, March 25, 1957, 298 U.N.T.S. 3 (effective Jan. 1, 1958) [hereinafter EEC Treaty]. An English translation is located at 1 Comm. Mkt. Rep. (CCH) ¶ 151 (1971).

9. Added by Article 13 of the Single European Act, 30 O.J. Eur. Comm. (No. L 169) 1 (1987), Feb. 1986 [hereinafter SEA].

10. *See, e.g.*, Cullet v. Centre Leclerc, 1985 E. Comm. Ct. J. Rep. 305; Procureur du Roi v. Dassonville, 1974 E. Comm. Ct. J. Rep. 837.

11. *See, e.g.*, Commission v. Ireland, 1982 E. Comm. Ct. J. Rep. 4005.

cal product regulations and testing and certification procedures also fall under the heading of "measures having equivalent effect." Technical standards which are not issued by member states but adopted by private standards bodies are not prohibited by Article 30 which only applies to member states.[12] However, the obligatory use of products certified as conforming to a particular national standard violates Article 30.[13]

Article 36 embodies the statutory exception to the prohibition of "measures having equivalent effect." It allows member states to maintain restrictions on exports and imports for reasons of "public morality, public policy or public security, the protection of health and life of humans, animals or plants, the protection of national treasures possessing artistic, historic or archaeological value, or the protection of industrial and commercial property." Such restrictions may not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between member states.

The judge-made exceptions are embodied in the *Cassis de Dijon* case law, so called after the 1979 seminal judgment of the Court dealing with the importation of *Cassis de Dijon* into West Germany. In this case, the German authorities prohibited the marketing in Germany of the French alcoholic beverage *Cassis de Dijon* under the name "liqueur," as the product did not have an alcohol content of at least 25%. The Court ruled that such refusal was, under the circumstances, an infringement of the EEC Treaty.[14]

In general, the *Cassis de Dijon* case law requires, in the absence of EC harmonization, each member state to permit goods lawfully manufactured and marketed in another member state to be imported and marketed, even if these goods do not satisfy their laws. If, however, the purpose of the law is to safeguard certain legitimate interests, the state will not be required to allow importation and marketing.[15] So far, the Court of Justice has indicated that "legitimate interests" include the following:

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12. *See, e.g.*, P. KAPTEYN & P. VER LOREN VAN THEMAAT, INTRODUCTION TO THE LAW OF THE EUROPEAN COMMUNITIES 380 (1989); White, *In Search of the Limits to Article 30 of the EEC Treaty*, 26 COMMON MKT. L. REV. 235, 265 (1989).

13. Commission v. Ireland, 1988 E. Comm. Ct. J. Rep. 4929.

14. Rewe-Zentral AG v. Bundesmonopolverwaltung für Branntwein, 1979 E. Comm. Ct. J. Rep. 649.

15. P. KAPTEYN & P. VER LOREN VAN THEMAAT, *supra* note 12, at 387; A. MATTERA, LE MARCHE UNIQUE EUROPEEN 190 (1988) (two introductory overviews of the *Cassis de Dijon* case law).

consumer protection, prevention of unfair commercial practices, effectiveness of fiscal supervision, environmental protection, improvement of working conditions, protection of public health or the promotion of culture.[16] Such restrictive measures must be uniformly applicable to domestic and imported goods and be proportionate and necessary to the intended goal. Finally, if there are less restrictive means of attaining the legitimate goal, the measures run afoul of EC law.[17]

The Court of Justice has ruled that requiring strict and exact compliance is contrary to the principle of proportionality. If the imported products comply with the technical requirements of the exporting state, and the exporting state affords the users a level of protection equivalent to that of the importing state, importation should be allowed.[18]

The Court of Justice has followed a similar approach with regard to conformity assessment procedures. In *Biologische Produkten*, the Court held that, in the absence of harmonization, member states have the right to require products to be subject to prior approval, even if those products have already been approved in another member state. The Court added, however, that the importing state is not entitled to require analyses or laboratory tests when the same analyses or tests have already been carried out in another member state and their results are available to those authorities or may be placed at their disposal upon request.[19]

These cases illustrate the approach of mutual recognition of legislation and controls. Member states are restrained from interfering with intra-EC trade; their discretion in imposing product requirements and conformity assessment controls on imports is effectively restricted. The cases also make it clear that the provisions of the EEC Treaty alone will not achieve free movement--member states may enact technical regulations insofar as these regulations meet the Article 36 test and the judge-made restrictions of the *Cassis de Dijon* case law. The states also may

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16. P. KAPTEYN & P. VER LOREN VAN THEMAAT, *supra* note 12, at 389.

17. Similar tests apply with regard to Article 36. *See, e.g.*, A. MATTERA, *supra* note 15, at 218, 516.

18. Commission v. France, 1986 E. Comm. Ct. J. Rep. 419. *See also Application of the "Mutual Recognition" Principle to Industrial Products*, Press Release of the EC Commission, June 1988.

19. 1981 E. Comm. Ct. J. Rep. 3277.

require testing and certification if such procedures meet the test of the *Biologische Produkten* case law.

In order to eliminate these remaining technical barriers, EC legislation must harmonize technical regulations and conformity assessment procedures, with a view to justifying the confidence member states are required to have in the laws of each other. The Court of Justice, however trade-liberalizing its case law may be, cannot offer more than a case-by-case liberalization. The Court is sometimes requested to decide issues of such a political, scientific or technical nature that one must genuinely wonder whether the judiciary is the institution best placed to make such determinations.

III. The Legal Basis for Harmonization in the EEC Treaty

The EEC Treaty recognizes the need for harmonizing national laws in order to achieve a truly common market.[20] Since 1957, Article 100 has laid down the legal procedure for adopting the required EC harmonization legislation. The Single European Act,[21] which took effect in July 1987, introduced a new Article 100a which embodies the procedure to be followed in adopting legislative measures for completing the internal market.[22] These articles are reviewed below.

Article 100 of the EEC Treaty provides that the Council of Ministers may, by a unanimous vote, adopt directives for the approximation of national laws and regulations which directly affect the establishment or functioning of the Common Market. The European Parliament and the Economic and Social Committee must be consulted in most cases. By contrast, the new Article 100a allows the Council of Ministers to act with only a qualified majority. The Council must do so in cooperation with the European Parliament and is required to consult the Economic and Social Committee.[23]

The differences between the two provisions are important. First, Article 100 requires that the approximation measures be adopted under the form of directives; Article 100a allows proposals to be in the form of directives or regulations. Regulations

20. *See, e.g.*, EEC Treaty, *supra* note 8, art. 3(h).
21. SEA, *supra* note 9.
22. Article 100a of the EEC Treaty was added by article 18 of the SEA.
23. EEC Treaty, *supra* note 8, art. 149, *as replaced by* SEA, *supra* note 9, art. 7.

allow less involvement of member states.[24] However, in a declaration on the Single European Act, the EC Commission gave an assurance that it would "give precedence to the use of the instrument of a directive if harmonization involves the amendment of legislative provisions in one or more member states."[25]

Second, Article 100a grants a greater involvement in the legislative process to the European Parliament than does Article 100.

Finally, and probably of most practical importance, the quorum required to achieve adoption of a proposed directive differs. Article 100 requires unanimity while Article 100a allows adoption by a qualified majority. Qualified majority voting requires that the votes of the different member states be weighted in order to take into consideration the relative importance of each member state. A qualified majority consists of 54 votes out of a total number of weighted votes of 76, divided as follows: France, Germany, Italy, and the United Kingdom each have 10 votes; Spain has 8 votes; Belgium, The Netherlands, Greece and Portugal each have 5 votes; Denmark and Ireland each have 3 votes and Luxembourg has 2 votes.[26]

Majority voting has already made a difference in Council negotiations. The threat of not being able to rally enough allies in a final vote to defeat a proposal forces member states to look constructively for a negotiated solution. However, the threshold needed for a qualified majority (54 out of 76 votes) is high. Two larger member states and one smaller member state, or one larger and three smaller, will in most cases suffice to prevent adoption.

The provision for majority voting under Article 100a explains a host of restrictions which are intended to protect member states which take a minority position.[27]

The Commission is required to use a high level of protection as a basis in its proposals concerning health, safety, environmental protection and consumer protection.[28] This provision was included at the insistence of those member states such as Germany and Denmark which have well-developed legislation in the

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24. EEC Treaty, *supra* note 8, art. 189.

25. SEA, *supra* note 9, Declaration on Article 100a, at 24.

26. EEC Treaty, *supra* note 8, art. 148.

27. *See, e.g.*, Ehlermann, *The Internal Market Following the Single European Act*, 24 COMMON MKT. L. REV. 361 (1987).

28. SEA, *supra* note 9, art. 100a, para. 3.

above mentioned fields. The only sanction for non-observance of this provision by the Commission seems to be the application of the safeguard clause of Article 100a, paragraph 4, discussed below.

Furthermore, Article 100a provides the possibility of including a safeguard clause in the harmonization measure. The clause authorizes member states to take, for one or more of the non-economic reasons referred to in Article 36, provisional measures subject to an EC control procedure.[29] This procedure adds nothing new; it merely describes a practice which already existed in the harmonization directives based on Article 100.

In contrast, Article 100a introduces a new safeguard procedure which only applies after the adoption of a harmonization measure.[30] This safeguard procedure was drafted by the European Council of Heads of State and Government itself and can be seen as a counterweight to the adoption of a qualified majority voting system. Under this new procedure, member states may, after the adoption of a harmonization measure, apply national provisions on grounds of the major needs referred to in Article 36 of the EEC Treaty or relating to the protection of the environment or working conditions. Consumer protection is notably deleted from this list so that national measures based on consumer protection cannot be invoked against an EC measure.

A member state which wishes to invoke the safeguard clause has to notify the Commission of these national provisions. The Commission verifies that they are not a means of arbitrary discrimination or a disguised restriction on trade between member states, and confirms them, if appropriate. If the Commission, or any member state, considers that a member state is improperly invoking the safeguard clause, they can bring the matter directly before the Court of Justice.

IV. From the General Program to the New Approach

In May 1969, the Council of Ministers adopted a General Program on the elimination of technical barriers to trade resulting from divergent national laws.[31] According to this ambitious program, the EC was to adopt, before the end of 1970, a host of harmonization directives regarding motor vehicles, agricultural

29. *Id.*, para. 5.
30. *Id.*, para. 4; *see also* Ehlermann, *supra* note 27, at 389.
31. *See supra* note 1.

and forestry tractors, pressure vessels, measurement instruments, electric machines and equipment, etc.

The EC institutions intended to eliminate these technical barriers through either total or optional harmonization. In the case of total harmonization, the products covered by the directive have to satisfy the technical specifications. This results in member states losing their powers to issue technical specifications after the enactment of the EC legislation. In the case of optional harmonization, products satisfying harmonized technical specification circulate freely throughout the EC. Although member states retain their powers to issue divergent national technical specifications, these specifications can no longer be enforced against products imported from other member states.[32]

Each of the directives provided for the definition, product by product, of the technical specifications which had to be harmonized. For example, Council Directive 70/156/EEC provides harmonized motor vehicle specifications.[33] Motor vehicles which satisfy these specifications will be eligible for EEC vehicle type approval. Once such type approval is obtained, the motor vehicle can be put on the market throughout the EC. Council 70/156 is a framework directive which specifies areas of harmonization. Since its adoption, over forty directives have been adopted covering such areas as defrosting and demisting systems for glazed surfaces of motor vehicles,[34] reflex reflectors,[35] safety belts and restraint systems.[36] Each directive often contains a long list of detailed technical specifications. Because a few directives are still outstanding,[37] no internal market for motor vehicles exists. Member states can still enforce national standards against imported motor vehicles in areas where harmonization is lacking. However, it should be remembered that the Court of Justice has held that member states may not require imported products to literally and exactly meet their technical requirements or char-

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32. *See also* A. MATTERA, *supra* note 15, at 149.

33. 13 J.O. COMM. EUR. (No. L 42) 1 (1970).

34. *Council Directive 78/371/EEC*, 21 O.J. EUR. COMM. (No. L 81) 27 (1978).

35. *Council Directive 77/539/EEC*, 20 O.J. EUR. COMM. (No. L 220) 72 (1977).

36. *Council Directive 77/541/EEC*, 20 O.J. EUR. COMM. (No. L 220) 95 (1977). For a list of these directives see I Directory of Community Legislation in Force 650 (15th ed. 1990).

37. The last three proposals were submitted by the Council of Ministers in February 1990. *See* 33 O.J. EUR. COMM. (No. C 95) 1, 92, 101 (1990).

acteristics so long as the imported products guarantee the same level of safety for users.[38]

Although this approach has led to (sometimes incomplete) results in certain sectors, it has proved difficult and the results were certainly below expectations. Reasons for its difficulty and poor results may be due to the fact that many of the adopted directives are excessively complex, sometimes fragmentary, and sometimes even outdated at the time of their adoption. In addition, many sectors remained outside the reach of EC harmonization efforts. In order to obtain unanimity, the content of the traditional harmonization measures was more often a sum of all national ideas rather than a well-balanced compromise. Finally, it is interesting to note that in certain cases, the European Parliament refused to render an opinion, finding that it was not competent to review such detailed technical issues.

When the Court of Justice developed its *Cassis de Dijon* case law, which called for mutual recognition of legislation and controls, the Commission realized the potential for progress in technical harmonization.[39] In the early 1980's, the Commission developed, on the basis of the Court's case law, a new harmonization strategy which forms the core of its 1985 White Paper.[40] The essentials of this new approach are explained below.

In its Resolution of May 7, 1985 ("1985 Council Resolution") the Council of Ministers endorsed a new strategy for the elimination of technical barriers and called upon the Commission to submit suitable proposals.[41] The guidelines for a new approach to technical harmonization and standards are published in an annex to the 1985 Council Resolution, and will be discussed hereafter. In its Resolution, the Council asks the Commission to develop an EC policy on conformity assessment. The Commission response is found in a recent communication to the Council on a global approach to certification and testing.[42] This

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38. *See also Commission Notice on Procedures for the Type-Approval and Registration of Vehicles Previously Registered in Another Member State*, 31 O.J. EUR. COMM. (No. C 281) 9 (1988).

39. *See, e.g., Communication from the Commission Concerning the Consequences of the Judgment Given by the Court of Justice on 20 February 1979 in Case 120/78* ("Cassis de Dijon"), 23 O.J. EUR. COMM. (No. C 256) 2 (1980).

40. *See supra* note 3, at 19.

41. *Council Resolution of 7 May 1985 on a New Approach to Technical Harmonization* [hereinafter *1985 Council Resolution*] 28 O.J. EUR. COMM. (No. C 136) 1 (1985).

42. *A Global Approach to Certification and Testing (Commission Communication to the Council)* [hereinafter *1989 Memorandum*], 32 O.J. EUR. COMM. (No. C 267) 3

communication and subsequent action in this matter is dealt with in Section VII.

This new approach to technical harmonization and standards incorporates a blend of three legislative harmonization measures: mutual recognition, harmonization and reference to standards. Its main features are as follows:

1) EC legislation will be limited to the adoption of essential safety and health requirements (or possibly other essential requirements in the general interest). Products which meet these "essential requirements" must be allowed to circulate freely throughout the EC. The new approach directives should encompass wide product categories and types of risk;

2) member states must transpose these "essential requirements" into their national law by the deadline set by the directive. Therefore, the "essential requirements" must be specific enough to enable certification bodies to certify products as being in conformity, even in the absence of standards;

3) the task of drawing up technical specifications (i.e. harmonized standards) implementing the essential requirements established in the directives is entrusted to standardization bodies, in principle the European Committee for Standardization ("CEN") or the European Committee for Electrotechnical Standardization ("CENELEC"). Until harmonized standards are issued, the Commission may declare that national standards which have been notified to it satisfy the essential requirements; and

4) a manufacturer is not required to comply with the harmonized standards (or, provisionally, the national standards which have been declared equivalent). Products manufactured in conformity with such standards, however, are presumed to meet "essential requirements." A product which is not manufactured in conformity with such standards will not be allowed to circulate freely within the EC, unless proven to conform to the "essential requirements."

It should be understood that the new approach is only applied to sectors which are particularly suited to and heavily dependent upon the "reference to standards" method.[43] Under this method, the EC institutions lay down essential requirements

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43. *Annex II to 1985 Council Resolution*, 28 O.J. EUR. COMM. (No. C 136) 2, 8 (1985) [hereinafter *1985 Guidelines*].

which are to be matched with European standards by standardization bodies. The old approach continues to be used to complete harmonization in sectors where a change of method would be impossible in view of the progress already made. An obvious example is the motor vehicles sector, where the Commission has recently submitted proposals to cover areas lacking harmonization.[44]

The 1985 Council Resolution also indicates areas where harmonization is most desirable, such as building materials and many engineering products.[45] On November 1, 1990, the Council of Ministers adopted the following directives applying to broad categories of products: simple pressure vessels,[46] toys,[47] construction products,[48] electromagnetic compatibility,[49] machinery,[50] personal protective equipment,[51] active implantable medical equipment,[52] appliances burning gaseous fuels,[53] and non-automatic weighing instruments.[54]Proposals are pending before the Council of Ministers with regard to mobile machinery,[55] telecommunications terminal equipment,[56] and lifting and mobile equipment.[57]

V. The Structure of a New Approach Directive

The guidelines for a new approach, published in an annex to the 1985 Council Resolution ("1985 Guidelines"), outline the structure for new approach directives. This structure is discussed below. It should be borne in mind that specific new approach directives may not entirely satisfy the structure set out hereafter.

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44. *See supra* notes 34-37 and accompanying text.
45. *1985 Guidelines*, *supra* note 43, at 8.
46. *Council Directive 87/404/EEC*, 30 O.J. Eur. Comm. (No. L 220) 48 (1987).
47. *Council Directive 88/378/EEC*, 31 O.J. Eur. Comm. (No. L 187) 1 (1988).
48. *Council Directive 89/106/EEC*, 32 O.J. Eur. Comm. (No. L 40) 12 (1989).
49. *Council Directive 89/336/EEC*, 32 O.J. Eur. Comm. (No. L 139) 19 (1989).
50. *Council Directive 89/392/EEC*, 32 O.J. Eur. Comm. (No. L 183) 9 (1989).
51. *Council Directive 89/686/EEC*, 32 O.J. Eur. Comm. (No. L 339) 18 (1989).
52. *Council Directive 90/385/EEC*, 33 O.J. Eur. Comm. (No. L 189) 17 (1990).
53. *Council Directive 90/396/EEC*, 33 O.J. Eur. Comm. (No. L 196) 15 (1990).
54. *Council Directive 90/384/EEC*, 33 O.J. Eur. Comm. (No. L 189) 1 (1990).
55. 32 O.J. Eur. Comm. (No. C 70) 6 (1989).
56. 33 O.J. Eur. Comm. (No. C 187) 40 (1990).
57. 33 O.J. Eur. Comm. (No. C 37) 5 (1990).

A. *Scope*

Each directive defines the range of products covered and the nature of the hazards which the directive is intended to avert.[58] The 1985 Guidelines mention safety, health, and consumer or environmental protection as essential requirements,[59] but the category of essential requirements is open. Each directive must set the essential requirements to be met in an annex.

A critical issue, however, remains the distinction between essential requirements and technical specifications. Where this distinction cannot properly be made, the new approach is of little use, as the directives specifying the essential requirements are overly detailed. The 1985 Guidelines specify that the essential requirements must be worded with sufficient precision so that they can, after incorporation into national law, create legally binding obligations. The essential requirements should be formulated so as to enable the certification bodies to immediately certify products as being in conformity, even in the absence of standards.[60]

The content of the essential requirements remains a debated issue. Some regret the stress on health and safety aspects, and fear impoverishment of more comprehensive national standards which take, for example, noise, energy savings and durability requirements into account.

The definition of the products covered by the new approach directive is broad. For example, for the purpose of the machinery directive, "machinery" means "an assembly of linked parts or components, at least one of which moves, with the appropriate actuators, control and power circuits, etc., joined together for a specific application, in particular for the processing, treatment, moving or packing of a material" as well as "an assembly of machines which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole."[61] For the purpose of the construction products directive, "construction products" is defined as "any product which is produced for incorporation in a permanent manner in construction works, including buildings and civil engineering works."[62]

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58. *1985 Guidelines*, *supra* note 43, at 4; *see, e.g.*, *Council Directive 89/392/EEC*, *supra* note 50, art. 1 & annex I.

59. *1985 Guidelines*, *supra* note 43, at 3, 4.

60. *Id.* at 4.

61. *Council Directive 89/392/EEC*, *supra* note 50, art. 1(2).

62. *Council Directive 89/106/EEC*, *supra* note 48, art. 1(2).

The broad scope of the directives allows certain products to be covered by two or more harmonization directives. The product must then satisfy essential requirements of all applicable directives according to the type of hazard associated with that product.

B. Placing on the Market

Member states are instructed to ensure that products covered by a directive are placed on the market only if they do not endanger personal health or safety, and, where appropriate, the safety of domestic animals or property must not be endangered.[63] In certain situations, namely those where protection of workers and consumers is an issue, the conditions set out in this clause may be strengthened to include foreseeable use.[64]

Furthermore, the new approach directives provide that all products covered must satisfy essential requirements. In other words, the new approach directives go beyond optional harmonization. Products which do not meet the essential requirements may no longer be put into any EC market. Optional harmonization would allow products which fail to satisfy the essential requirements to be put into the market (provided national legislation would so permit) but other member states could prevent importation.[65] In the past, technical harmonization directives have often used an optional harmonization method, but the new approach no longer endorses it.

It should be clear that this does not mean that products must be manufactured according to European standards. However, as will be mentioned later, if products do not meet European standards, the manufacturer or his legal representative will have to prove that the essential requirements are met.

C. Free Movement

The new approach directives require member states to accept, under the conditions regarding proof of conformity, the

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63. *1985 Guidelines*, *supra* note 43, at 4; *see, e.g.*, *Council Directive 89/392/EEC*, *supra* note 50, art. 2.

64. *1985 Guidelines*, *supra* note 43, at 4; *see, e.g.*, *Council Directive 88/378/EEC*, *supra* note 47, art. 2(1) (providing that toys may only be placed on the market if they do not jeopardize the safety and/or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the normal behavior of children).

65. *1985 Guidelines*, *supra* note 43, at 4; *see, e.g.*, *Council Directive* 89/106/EEC, *supra* note 48, art. 2(1).

free movement of products which meet the essential requirements.[66] This requirement will result in the abolition of technical barriers. Because the new approach directives provide, as a general rule, for total harmonization, any product (whether it is domestically produced or imported) must be allowed to be put on the market if it meets the essential requirements laid down in the directive.

As a result, member states will not only be prevented from enforcing stricter requirements against imported products; they are no longer allowed to impose these stricter requirements on domestic products. Thus, while a situation of "reverse discrimination" (i.e. subjecting products manufactured in the member state to stricter requirements than imported products) is compatible with Article 30 of the EEC Treaty,[67] such a situation is precluded once harmonization has occurred under a directive imposing total harmonization.[68]

In principle, member states will no longer be entitled to rely on the *Cassis de Dijon* case law[69] nor on the statutory exceptions of Article 36 of the EEC Treaty.[70] An interesting question nevertheless remains: May the member state still impede the placing on the market of a product, e.g., for environmental reasons, if a directive has laid down essential health and safety requirements? It is probable that the member state should invoke the safeguard clause in Article 100a, para 4, provided all conditions are met.[71] Moreover, on the basis of Article 100a, para. 5,[72] the new approach directives sometimes explicitly allow a member state to intervene.[73] The intervention, however, must not

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66. *1985 Guidelines*, *supra* note 43, at 5; *see, e.g., Council Directive 89/336/EEC*, *supra* note 49, art. 5.

67. *See, e.g.,* Ministère Public v. Mathot, 1987 E. Comm. Ct. J. Rep. 809; Nederlandse Bakkerij Stichting v. Edah, 1986 E. Comm. Ct. J. Rep. 3359.

68. *See, e.g.*, SARPP v. Chambre syndicale des raffineurs et conditionneurs de sucre de France Case C-241/89 (Dec. 12, 1990); Driancourt v. Cognet, 1986 E. Comm. Ct. J. Rep. 3231.

69. The *Cassis de Dijon* case law explicitly holds that member states may only invoke the protection of the legitimate interests recognized by the Court of Justice in the absence of EC harmonization. *See* Rewe-Zentral AG v. Bundesmonopolverwaltung fur Branntwein, 1979 E. Comm. Ct. J. Rep. 649; *see also supra* text accompanying note 14. For the exceptions of Article 36 of the EEC Treaty, see SEA, *supra* note 9, at para. 5, and text accompanying note 29.

70. *See, e.g.*, Van Bennekom, 1983 E. COMM. CT. J. REP. 3883.

71. *See supra* note 30 and accompanying text.

72. *See* SEA, *supra* note 9, at para. 5, and text accompanying note 29.

73. *Council Directive 89/336/EEC*, *supra* note 49, art. 5, which provides: "Member States shall not impede for reasons relating to electromagnetic compatibility the placing

modify the product into non-conformity with directive provisions. Such further regulation must obviously conform with the EEC Treaty.[74]

D. Means of Proof of Conformity and Effects

The new approach directives require member states to presume that goods put into the market meet the essential requirements as long as they are accompanied by an approved means of proof declaring their conformity with harmonized standards set by a competent European standardization body.[75]

Sometimes the directives require that national standards recognized by the EC Commission carry the same presumption of conformity.[76] This requirement is a transitional measure for areas where harmonized standards do not exist.[77] For this purpose, member states may communicate to the Commission the texts of their national standards which they regard as complying with the essential requirements as stated in the directive. The Commission forwards these standards to the other member states and to a committee of national experts for examination. The Commission must publish reference numbers to these standards in the Official Journal. Likewise, the member states must publish these reference numbers.[78] It is the Commission which finally decides the equivalence of national standards.

As mentioned, manufacturers do not have to conform to the standards. In practice standards may not yet exist. Member states are nevertheless required to allow the marketing of such products if conformity is declared by the proper means of certification.[79] The harmonized standards (or provisionally recognized national standards) maintain their non-mandatory character.

The voluntary character of the technical standards also leaves the manufacturer's liability unimpaired. Indeed, Council

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on the market . . . ." (In this case it must be assumed that member states may still regulate even outside the scope of Article 100a). *See also Council Directive 89/392/EEC, supra* note 50, art. 2(2); *Council Directive 89/686/EEC, supra* note 51, art. 2(2).

74. *See, e.g.*, SARPP v. Chambre syndicale des raffineurs et conditionneurs de sucre de France, Case C-241/89 (Dec. 12, 1990).

75. *1985 Guidelines, supra* note 43, at 5; *see, e.g., Council Directive 89/686/EEC, supra* note 51, art. 5.

76. *1985 Guidelines, supra* note 43, at 5; *see, e.g., Council Directive 89/336/EEC, supra* note 49, art. 7.1.

77. *1985 Guidelines, supra* note 43, at 5.

78. *Id.* at 5; *see, e.g., Council Directive 89/686/EEC, supra* note 51, art. 5.4.

79. *1985 Guidelines, supra* note 43, at 5.

Directive 85/374/EEC on product liability only clears the manufacturer of his liability in the case of a defect due to "compliance with mandatory regulations issued by public authorities."[80] On the other hand, the Commission's proposal for a Council Directive concerning general product safety presumes a product to be safe when it is manufactured in accordance with the relevant national or European health and safety requirements.[81]

E. Safeguard Clause

Each new approach directive contains a set of safeguard clauses. Where a member state finds that a product might compromise the safety of individuals, domestic animals or property, it must take all appropriate measures to withdraw the products from the market. The member state may also prohibit marketing of the product or restrict its free movement, even if accompanied by an approved conformity form.[82]

If the product bears the EC mark, the member state must immediately inform the EC Commission of such a measure, indicating the reasons for its decision. The member state must also announce whether the non-conformity results from:

1) failure to comply with the essential requirements;

2) incorrect application of the (harmonized or provisionally recognized national) standards; or

3) shortcomings in the standards themselves.[83]

The Commission must consult the parties concerned as soon as possible. Where the Commission considers, after this consultation, that the measure is justified, it must immediately inform the member state which took the initiative and all other member states. If, after this consultation, the Commission decides that the action is unjustified, it must immediately inform the member state which took the initiative and the manufacturer of the product.[84]

If the member state has taken measures because of shortcomings in standards and intends to maintain such measures af-

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80. 28 O.J. EUR. COMM. (No. L 210) art. 7(d), at 29 (1985).

81. 33 O.J. EUR. COMM. (No. C 156) art. 4, at 8 (1990).

82. *1985 Guidelines*, *supra* note 43, at 6; *see, e.g.*, *Council Directive 89/392/EEC*, *supra* note 50, art. 7.

83. *1985 Guidelines*, *supra* note 43, at 6; *see, e.g.*, *Council Directive 88/378/EEC*, *supra* note 47, art. 7(1).

84. *1985 Guidelines*, *supra* note 43, at 7; *see, e.g.*, *Council Directive 89/392/EEC*, *supra* note 50, art. 7(2).

ter the consultations, the Commission must refer the matter immediately to a competent committee of experts. Upon receipt of the committee's opinion, the Commission must inform the member states whether it is necessary to withdraw those standards from the published information. The Commission may also decide to issue a new standardization mandate to CEN/CENELEC or some other appropriate standardization body.[85]

The outlined procedure subjects the member states' power to restrict free circulation of goods to strict EC control rules. The procedure also avoids creation of new technical barriers, while allowing member states and the Commission to upgrade or update specific technical standards. For this purpose, the Commission or any member state may bring a harmonized standard for review before the competent committee of experts if it believes that the harmonized standard does not entirely satisfy the essential requirements laid down in the directive.

According to the *Cremonimi and Vrankovich* judgment of the Court of Justice,[86] courts may no longer intervene to prevent the importation of goods bearing an EC mark. Member states must resort to the safeguard clause.

F. Forms of Attestation of Conformity

The new approach directives contain provisions setting forth the means of attesting compliance with the essential requirements. The 1985 Guidelines provide for the following means of attestation:

1) certificates and conformity marks issued by a third party;

2) tests results carried out by a third party;

3) declaration of conformity issued by the manufacturer or an authorized EC representative (this may be coupled with the requirement of a surveillance system); or

4) other means of attestation, possibly determined in the directive.[87]

The exhaustive list of attestation forms affects only the presumption of conformity, it cannot restrict a member of the trade

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85. *1985 Guidelines*, *supra* note 43, at 7; *see, e.g.*, *Council Directive 89/392/EEC*, *supra* note 50, arts. 7(2) and 6(1).

86. 1980 E. Comm. Ct. J. Rep. 3583.

87. *1985 Guidelines*, *supra* note 43, at 7.

from proving, by any means it sees fit, the conformity of the product.[88]

The innovative aspect of this new approach for conformity assessment is that it leaves the manufacturer a degree of flexibility in demonstrating conformity. If the manufacturer follows the harmonized standards, or provisionally recognized national standards, it may use a simplified procedure. If the product is manufactured directly to the essential requirements, third party intervention is required to ensure conformity.

Almost all the old approach directives (except the 1973 Low Voltage Directive)[89] provided for (1) the mutual recognition of certificates based on a single assessment method for a given product, and (2) the issuance of certificates by public authorities or under their direct responsibility.

Concerning the definition of the conformity assessment procedures, new approach directives adopted currently provide a remarkable variety. In 1989, after some years of experience with the new approach, the Commission submitted its Memorandum on a Global Approach to Certification and Testing.[90] This document complements the 1985 Council Resolution and is designed to bring some order into the field of conformity assessment as well as to endorse the most modern techniques developed. This Memorandum and the problems relating to certification and testing are discussed in Section VII.

G. The EC Mark

Before the new approach, EC directives provided for a number of EC marks which varied in significance. Under the new approach, there is a single EC mark.[91] It is intended that it will be adopted for all future EC legislation. The new EC mark has the same shape in all language versions and is followed by the last two digits of the year in which it is affixed.

The EC mark indicates exclusively, for control purposes, conformity to the essential requirements. It is not a quality mark. Since the EC mark certifies compliance with the directive concerned, its affixing is a necessary condition for placing the product on the market in the EC. Obviously, this obligation ap-

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88. *Id.*
89. 16 O.J. EUR. COMM. (No. L 77) 29 (1973).
90. *1989 Memorandum, supra* note 42.
91. *Id.* at 23.

plies equally to products originating in countries outside the EC. If a product is covered by several directives, the EC mark may only be affixed if the product conforms to all the directives involved. The EC mark does not indicate the directives and/or standards to which a product conforms or the conformity assessment procedure followed. An intervening third party may, however, affix its mark or seal next to the EC mark.

The EC mark may also co-exist with quality marks and with national marks which certify conformity with national standards. According to the Commission, national marks, indicating conformity to national regulations, are no longer allowed as the new approach directives replace all national regulations on the subject.[92] It seems more accurate to state that member states may no longer require imported products to bear national marks as a condition of putting the product into the market. Such national standards could indeed once again become *de facto* technical barriers.

The Commission intends to propose a directive which will set out the conditions governing the use and protection of the EC mark.[93]

VI. The European Standardization Bodies

The harmonization directives normally delegate the task of setting European standards to two European standards bodies: the European Committee for Standardization ("CEN") or the European Committee for Electrotechnical Standardization ("CENELEC"). Together, these two bodies form the Joint European Standards Institution. The European Telecommunications Standards Institute ("ETSI") controls telecommunications. In matters of information technology, the standards institutions work together through the Information Technology Steering Committee ("ITSTC"). The following discussion is limited to CEN and CENELEC.

A. Organization

CEN and CENELEC each consist of the national standards institutions of the twelve EC countries and the six European

92. *Id.* at 24.
93. *Id.*

Free Trade Association ("EFTA") countries.[94] Both CEN and CENELEC have their central secretariat in Brussels.

CEN is the European link between the International Organization for Standardization ("ISO") and the national (non-electrotechnical) standards bodies. CENELEC is the intermediate European level between the International Electrotechnical Committee ("IEC") and the national electrotechnical committees.

The technical work is done in technical committees. The secretariat of each committee goes to either a CEN or a CENELEC member. If possible, the secretariat in Europe is allocated to the member holding the secretariat of the corresponding ISO or IEC Committee.[95]

During the negotiations, CEN and CENELEC members undertake to not issue national standards in areas where European work is in progress or to take measures which may endanger the harmonization effort. This standstill agreement does not apply, however, when a European pre-standard is being prepared.[96]

The harmonized specifications are adopted by a qualified majority, although efforts are made to obtain unanimity. Weighing coefficients are based on Article 148 of the EEC Treaty for the EC member states. The coefficients are decided by common agreement for the EFTA countries.[97]

B. Types of Standards

The harmonization proceedings can result in three types of documents: European standards ("EN"), harmonization documents ("HD") and European pre-standards ("ENV"). The EN and HD are commonly referred to as "CEN standards" or "CENELEC standards."[98]

The EN and HD differ essentially in the degree of obligation they impose on the members. Both the EN and HD require implementation at the national level by giving it the status of a national standard. Any conflicting national standard must be withdrawn. However, the HD allows a member to maintain or issue a national standard on a subject within the scope of the HD, provided that it is technically equivalent. The HD also al-

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94. The EFTA is comprised of Austria, Finland, Iceland, Norway, Sweden, and Switzerland.

95. F. NICOLAS & J. REPUSSARD, *supra* note 4, at 28.

96. *Id.* at 30.

97. *Id.* at 40.

98. *See generally id.* at 30.

lows national deviations under special conditions. These deviations are normally temporary. In general, preference is given to adopting EN rather than HD standards so as to have an identical text in all countries.

It should be noted that the obligation to incorporate an EN or HD into national law exists for all CEN/CENELEC members, even those who may have voted against the adopted standard. When an EN or HD fails to pass in the vote, the EC member states' votes are tallied separately, and if the result is then positive (i.e. a qualified majority is reached amongst the member states), all the EC countries are obliged to implement the document. In addition, the EFTA countries which voted in favor of the EN or HD are obliged to implement it.

ENV's are prospective standards, applying temporarily (in principle 3 years, with a maximum of 5 years) in technical fields where the innovation rate is high and there is an urgent need for guidance. This category was created to meet the challenge of information technology. Members have to make the ENV available at the national level. However, existing national standards which conflict with the ENV may be kept in force until the final decision on the conversion of the ENV into an EN or HD is taken.

The CEN/CENELEC standards exist in their own right and are published in English, French and German, except for ENV's. However, it may initially be available in only one of the three languages. It should be remembered that although national standards institutions may be bound by EN's and HD's, compliance with these standards always remains voluntary for the industry unless the government imposes compliance by law.

C. Cooperation with the EC

The standardization policy followed by the EC is based on three fundamental documents:

1) Council Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations;[99]

2) Council Resolution of May 7, 1985 recommending reference to standards as a crucial element in the new approach to technical harmonization and standards;[100]

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99. *See supra* note 2.

100. *See 1985 Council Resolution, supra* note 41.

3) The Conclusions on standardization of the Council of Ministers of July 16, 1984 (joined as an Annex to the 1985 Council Resolution);[101]

In November 1984, relations between the Commission and CEN/CENELEC were formalized in general guidelines for mutual cooperation. On the basis of these guidelines, the Commission has concluded a framework agreement with CEN/CENELEC providing the general administrative, financial and legal conditions under which the specific standardization mandates will be implemented. The Commission implemented such standardization mandates under its new approach in areas such as toys and simple pressure vessels. In 1987, the Commission and CEN/CENELEC agreed that instead of working with case by case mandates, a general mandate could be conferred for a list of the standardization proceedings for the following three years.

D. A New Strategy for European Standardization

One result of the new approach is that standardization work is no longer the task of the legislative institutions of the EC. Instead, this task has been entrusted to the European standardization bodies. These bodies have done a lot of work since the adoption of the new approach. Over the last six years, they have adopted over 800 standards, three times as many as in the previous twenty years. The work that still needs to be done is, however, enormous, and it seems that the European standardization bodies cannot, in their present structure, keep up the pace.

As a response to this problem, in October 1990, the Commission published a *Green Paper on the Development of European Standardization*.[102] This paper is a compilation document addressed to all interested parties, in which the Commission proposes for discussion suggestions for improving the efficiency of standardization organizations as well as their cooperation and cohesion. With regard to the latter aspect, the Commission proposed the establishment of a new framework (the "European Standardization System"), and a redefinition of the tasks of the European and national standardization bodies. In the light of

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101. In addition to the principles dealt with in the documents listed in one and two, these conclusions call for a strengthening of European standardization capacity and the systematic preparation of European standards for new technologies.

102. COM (90) 456 final (1990) [hereinafter *Green Paper*].

the discussion of the *Green Paper*, the Commission will make formal proposals to the Council of Ministers during 1991.

VII. A New Approach to Conformity Assessment

A crucial element in the elimination of technical barriers is the assessment of a product's conformity with essential requirements. The 1985 Council Resolution allows the specific directives to define rules according to the nature of the products or hazards covered, or the custom in the trade and industry concerned. The 1985 Council Resolution nevertheless recognizes the importance of a global approach to conformity assessment, and calls upon the Commission to put forward suitable proposals to this end.[103]

As mentioned above, the Commission responded with its 1989 Memorandum entitled "A Global Approach to Certification and Testing."[104] On December 21, 1989, the Council of Ministers approved in a resolution, the guiding principles underlying the 1989 Memorandum.[105]

A. Conformity Assessment Procedures

In choosing the appropriate conformity assessment procedure, opposing interests come into play as to who should test and certify the conformity of a product. In other words, should conformity assessment be the responsibility of the manufacturer who remains liable for his products or should a third party be entrusted with this task? The new approach directives adopted to date have adopted a variety of different procedures.

In its 1989 Memorandum, the Commission proposes a modular approach subdividing conformity assessment procedures into a number of operations (modules) which differ according to (i) the stage of development of the product (e.g. design, prototype, full production); (ii) the type of assessment involved (e.g. documentary checks, type-testing, quality assurance, inspection); and (iii) who carries out the assessment (the manufacturer or various third parties).

Conformity assessment procedures normally come into play at two levels in the manufacturing process, the design stage and the production stage. The procedures have therefore been subdi-

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103. *1985 Council Resolution, supra* note 41, at 1.
104. *See 1989 Memorandum, supra* note 42.
105. 33 O.J. Eur. Comm. (No. C 10) 1 (1990).

vided into modules addressing each of these two levels. However, some modules which relate only to the production stage, may not be applied without the intervention of another module at the design stage. Other modules, however, automatically cover both the design and production phases.

In June 1989, the Commission tabled a proposal for a Council Decision concerning these modules. The proposal contains the following eight modules:[106]

1) *Module A—Internal production control*: (covers both the design and production phases) the manufacturer declares that the products concerned satisfy the essential requirements of the directive; the manufacturer affixes the EC mark to the products and draws up a written declaration of conformity; a file containing technical documentation is available to the public authorities for inspection;[107]

2) *Module B—EC type examination*: (covers only the design stage and must therefore be accompanied by a production module) an independent body ascertains and attests that a product specimen, representative of the production run, meets the essential requirements; upon approval, the body will issue an EC type examination certificate;

3) *Module C—Conformity to type*: (covers only the production phase and must follow the issuance of an EC type examination certificate) the manufacturer satisfies itself that the products concerned are in conformity with the type as described in the EC type examination certificate and meet the essential requirements laid down in the directive; the manufacturer affixes the EC mark to the products and draws up a written declaration of conformity;

4) *Module D—Production quality assurance*: (covers only the production phase and must follow the issuance of an EC type examination certificate) the manufacturer satisfies itself that the products concerned are in conformity with the type as described in the EC type examination and meet the essential requirements laid down in the directive; the manufacturer oper-

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106. 32 O.J. EUR. COMM. (No. C 231) 3 (1989), *as amended by* 33 O.J. EUR. COMM. (No. C 179) 13 (1990). The Common Position of June 20, 1990 expressed an intent to adopt a decision concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives. DOC. 7067/90.

107. The Common Position provides for a module Aa adding to Module A a few additional checking requirements to be carried out by an independent body.

ates an approved quality system for manufacturing, final production inspection and testing (such as that described in EN 29002) and is subject to EC surveillance; the manufacturer affixes the EC mark to the products and draws up a written declaration of conformity; the EC mark is accompanied by the identification symbol of the independent body which carries out the EC surveillance;

5) *Module E—Product quality assurance*: (relates to the production phase only; it is normally carried out in conjunction with an EC type examination, but may, in special cases, be carried out alone) the manufacturer satisfies itself that the products concerned are in conformity with the type as described in the EC type examination certificate or with the essential requirements (where EC type certification is not required under the directive); it operates an approved quality system for final product inspection and testing (such as that described in EN 29003) under which all products are individually examined and appropriately tested; it is subject to EC surveillance and affixes the EC mark to the products and draws up a written declaration of conformity; the EC mark is accompanied by the identification symbol of the independent body which carries out the EC surveillance;

6) *Module F—Product verification*: (relates to the production phase only and is normally carried out in conjunction with an EC type examination) an independent body checks and attests that the products are in conformity with the technical documentation (when EC type examination is not required under the directive) or with the type as described in the EC type examination certificate and, in both cases, that the products satisfy the essential requirements laid down in the directive; the manufacturer may choose statistical verification under certain circumstances; the independent body or the manufacturer, according to the provisions of the directive, affixes the EC mark to the products and draws up a written certificate of conformity; the EC mark is accompanied by the identification symbol of the notified body;

7) *Module G—Unit verification*: (covers both the design and production phases, normally used for unit production or production in small series) an independent body checks and attests that individual products are in conformity with the essential requirements of the applicable directive; the body affixes the EC mark to the products and draws up a written certificate of

conformity; the EC mark is accompanied by the identification symbol of the intervening body; and

8) *Module H—Full quality assurance*: (covers both the design and production phases) the manufacturer ensures and declares that the products concerned satisfy the essential requirements laid down in the directive; it operates an approved quality system for design, manufacture and final production inspection and testing (such as that described in EN 29001); the directive may, in certain circumstances, require the manufacturer to request an independent body to examine and approve the conformity of the design to the essential requirements; the manufacturer is subject to EC surveillance and affixes the EC mark to the products and draws up a written declaration of conformity; the EC mark is accompanied by the identification symbol of the body which carries out the EC surveillance.

It should be noted that the 1989 Memorandum does not explicitly say which of these eight modules is the preferred means of conformity assessment. It does not, for example, state that Module A should be accepted in all directives as an option unless there is such an extreme risk that public assurance by a third party is required.

The Commission proposes that, in the future, technical harmonization directives should simply refer to one or more of the listed modules, according to the type of risk, the infrastructure in the particular sector, the characteristics of the product and the production process. The directive should, as a general rule, avoid fixing only one conformity assessment procedure for a given product, and rather confine itself to determining the different means for assessing conformity and the conditions in which they can apply.[108] The final choice between the permitted procedures should be left to the manufacturers themselves.

B. Mutual Recognition of Conformity Assessment Results

The various modules provide for the involvement of independent bodies at different levels (type-examination, product surveillance, approval of quality assurance, verification). They can be subdivided into testing laboratories, certification bodies and inspection bodies. The aim of the EC Commission is to achieve full mutual recognition of conformity assessment results, in the regulated sector, where such recognition can be imposed,

108. *Id.*

as well as in the non-regulated sector, where mutual recognition must come about voluntarily.[109] However, such mutual recognition requires that public authorities, consumers and users have sufficient confidence in the competence of laboratories and bodies. The Commission's goal is ambitious in light of the fact that Europe has over 10,000 testing laboratories and 1,000 certification bodies of varying capacity, legal status and reputation.[110]

The Commission proposes several measures for achieving the necessary degree of confidence. As far as the technical harmonization directives are concerned, it proposes that directives which require general criteria to be met by testing, inspection and certification bodies are sufficient. It will then be the task of each member state to designate such bodies and notify the Commission and the other member states of them. Where the notified bodies can demonstrate that they satisfy the criteria laid down in European standards (in principle accreditation to EN 45000 series), they should in principle be presumed to comply with the criteria laid down in the directive. If not, it will be up to the member state designating the body to provide equivalent proof to the EC Commission.[111]

Finally, the Commission advocated in its 1989 Memorandum the establishment of a European Organization for Testing and Certification ("EOTC") in order to provide information, experience, and a framework within which appropriate structures and agreements for the different industrial sectors could be negotiated. It is hoped that such an organization would offer the same solution to the problem of testing, inspection, and certification as CEN/CENELEC has offered to the problem of standards.[112] Under its authority, sectoral committees would negotiate mutual recognition agreements, set up accreditation systems, organize intercomparisons between laboratories, etc.

In December 1989, the Council of Ministers agreed to the setting up of EOTC,[113] which led to the signing of a Memorandum of Understanding on April 25, 1990 between CEN/CENELEC, the EFTA secretariat, and the Commission. This new organization has been set up within CEN/CENELEC for an experimental period expiring on December 31, 1992. In its Green

109. *1989 Memorandum, supra* note 42, at 15.
110. *Id.* at 12.
111. *Id.* at 23.
112. *Id.* at 25.
113. *See Green Paper, supra* note 102.

Paper, the Commission suggests a separation between the tasks of EOTC and the future European Standardization System.[114]

VIII. The Prevention of Technical Barriers

To create a barrier-free market, it is not sufficient to abolish existing barriers. New technical barriers may be created which do not fall within the scope of the existing provisions ensuring the free movement of goods.

The 1969 General Program contained an Agreement of the Representatives of the Governments of the member states concerning standstill and information of the Commission with regard to their draft technical regulations.[115] This standstill agreement was merely a gentlemen's agreement, not legally binding and addressing only public technical specifications. It could therefore not limit the enormous growth of national public and private standardization activities in the seventies.

For the purpose of monitoring the proliferation of new national technical standards and regulations, the EC Council of Ministers adopted Council Directive 83/189/EEC in 1983. The directive set forth a procedure for providing technical standards and regulations information.[116] The main purpose of this clarifying directive is to introduce a procedure whereby all national draft technical standards and regulations on industrial products, agricultural products, foodstuffs, medicinal products and cosmetics should be brought to the attention of the interested parties. It should be noted that the EFTA countries, which are all members of CEN/CENELEC, undertook the same obligations as their EC counterparts.[117]

According to the procedure, member states must give notice to the Commission of each proposed technical regulation and must suspend adoption for at least three months. The Commission must immediately notify the other member states of this draft regulation. If the Commission or a member state delivers an opinion within three months that the proposed regulation may constitute a barrier to the free movement of goods, the adoption must be suspended for six months from the date of

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114. *Id.* at 45.

115. 12 J.O. Comm. Eur. (No. C 76) 9 (1969), *as amended by* 16 O.J. Eur. Comm. (No. C 9) 3 (1973).

116. *Council Directive 83/189/EEC*, *supra* note 2.

117. *See* F. Nicolas & J. Repussard, *supra* note 4, at 40.

notification in order to allow consultation at the EC level. If the Commission believes that common measures would be in the EC's interests, it may announce its intention to propose a harmonization directive, in which case the notified measure may not be adopted within a year of notification. If the notification draft regulation relates to a subject covered by a proposal for a directive or regulation, the member state must refrain from adopting the technical regulation for a period of one year after submission of the proposal. In the case of an emergency, the member states can immediately enact a technical regulation. The Commission can take appropriate action in cases where improper use is made of this procedure.[118]

Likewise, national standardization bodies are required to inform the Commission, CEN/CENELEC and the other standardization bodies of their standardization programs and draft standards. All other standardization bodies may request to be directly involved in drawing up the standard or may ask that the activity take place at a European, rather than a national level. Pursuant to such a request, the Commission may propose that CEN/CENELEC draw up a European standard. Member states must observe a standstill as to any national standardization activity which is the subject of the Commission's standardization request to CEN/CENELEC.[119]

According to a 1988 Commission report, about 3,500 standards (including those on which work is in progress) and about 200 regulations were notified to the Commission in 1987 (latest figures available).[120] It appeared, however, that the Commission was never notified of a large proportion of technical regulations adopted in the member states.

The Commission deems technical standards and regulations adopted in breach of Council Directive 83/189/EEC to be unenforceable against third parties.[121] The Commission also expects national courts to refuse to enforce such standards and regula-

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118. *Council Directive 83/189/EEC, supra* note 2, art. 8-10.

119. *Id.*, arts. 4-7.

120. *See Commission Report on the Operation of Directive 83/189/EEC Laying Down an Information Procedure in the Field of Standards and Technical Regulations, 1984-1987*, COM (88) 722 final.

121. *See Commission Communication Concerning the Non-Respect of Certain Provisions of Council Directive 83/189/EEC of 28 March 1983 Laying Down a Procedure for the Provision of Information in the Field of Technical Standards and Regulations*, 29 O.J. EUR. COMM. (No. C. 245) 4 (1986).

tions.[122] The Commission also has the right to start procedures under Article 169 of the EEC Treaty, if a member state fails to notify it of technical regulations or standards.

For the purpose of achieving clarity in the field of standardization, CEN/CENELEC has set up a database, called "Icone," which allows interested parties to compare the different national standards with each other as well as with the relevant international ISO/IEC and European standards.[123]

IX. Conclusion

The new approach to technical harmonization has revitalized the EC's ambitious technical harmonization program started in 1969. The new approach has been a centerpiece of the Commission plan to achieve a barrier-free market by the end of 1992 and has been an area in which the 1992 program has been successful. The results of the new approach have been spectacular, and almost all directives planned in the 1985 White Paper have already been adopted by the Council of Ministers.

The major breakthrough made possible by the new approach has been the separation of tasks to be carried out for the successful implementation of the technical harmonization program. The Commission, European Parliament, and the Council of Ministers make the political decisions as to the level of essential safety or health requirements. The setting of workable standards has been delegated to the European standardization bodies.

Over the last two years, attention has shifted to the enormous problems in implementing the new approach directives. Of particular concern is the ability of the European standardization bodies to prepare swiftly the European standards, which are essential to remove effectively the technical barriers as well as the procedures for determining conformity to the essential requirements. During the last months, it has become obvious that a major effort still remains to be performed which may delay the creation of a single European market for industrial products.

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122. *Id.*

123. *See generally* F. Nicolas & J. Repussard, *supra* note 4, at 39.